

**DRISTAN COLD MULTISYMP TOM- acetaminophen, chlorpheniramine maleate,
phenylephrine hcl tablet**
Wyeth Consumer Healthcare LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

DRISTAN[®] COLD MULTI-SYMP TOM

Drug Facts

<i>Active ingredients (in each tablet)</i>	<i>Purposes</i>
Acetaminophen, USP 325 mg	Pain reliever/Fever reducer
Chlorpheniramine maleate, USP 2 mg	Antihistamine
Phenylephrine HCl, USP 5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms associated with a cold, or flu:
 - headache
 - nasal congestion
 - sore throat
 - fever
 - minor aches and pains
- temporarily relieves minor aches, pains and headache as well as these symptoms of hay fever or other upper respiratory allergies:
 - runny nose
 - sneezing
 - nasal congestion
 - itching of the nose or throat
 - itchy, watery eyes
- temporarily relieves minor aches, pains, headache and nasal congestion as well as sinus congestion and pressure, and reduces swelling of nasal passages

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 tablets in any 24-hour period, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- to sedate a child or to make a child sleepy
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma
- a breathing problem such as emphysema, asthma, or chronic bronchitis

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking any other oral nasal decongestant or stimulant
- taking any other pain reliever/fever reducer
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

Stop use and ask a doctor if

- you get nervous, dizzy, or sleepless
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Directions

- do not use more than 12 tablets in any 24-hour period
- do not exceed recommended dosage. Taking more than the recommended dose (overdose) may

cause serious liver damage

- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	2 tablets every 4 hours
children under 12 years	do not use

Other information

- store at 20-25°C (68-77°F)
- tamper-evident individual blisters

Inactive ingredients

calcium stearate, croscarmellose sodium, crospovidone, D&C yellow no. 10 aluminum lake, FD&C yellow no. 6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid

Questions or comments?

Call weekdays from 9 AM to 5 PM EST at **1-800-535-0026**

Made in Canada

For most recent product information, visit www.dristan.com

Distributed by: Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 20 Tablet Blister Pack Carton

See new warnings information

Dristan[®]

Cold

Acetaminophen Pain reliever/Fever reducer

Chlorpheniramine maleate Antihistamine

Phenylephrine HCl Nasal decongestant

multi-symptom formula

**For relief of Nasal Congestion, Sinus Pressure, Headache,
Aches and Pains, Fever, Runny Nose and Sneezing**

20 COATED TABLETS

Drug Facts (continued)

Other Information (continued)

- tamper-evident individual blisters
- store at 20-25°C (68-77°F)

Drug Facts (continued)

Inactive ingredients calcium stearate, croscarmellose sodium, crospovidone, D&C yellow no. 10 aluminum lake, FD&C yellow no. 6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid

Drug Facts (continued)

Questions or comments?
 Call weekdays from 9 AM to 5 PM EST
 at 1-800-535-0126

age	dose
adults and children 12 years and over	2 tablets every 4 hours
children under 12 years	do not use

■ this adult product is not intended for use in children under 12 years of age
 ■ dose (overdose) may cause serious liver damage
 ■ do not exceed recommended dosage. Taking more than the recommended dose

Directions ■ do not use more than 12 tablets in any 24-hour period

Warnings

Liver warning: This product contains acetaminophen. More than 12 tablets in any 24-hour period, which is the maximum daily amount, with other drugs containing acetaminophen or 3 or more alcoholic drinks every day while using this product may cause severe liver damage.

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Drug Facts (continued)

Ask a doctor before use if you have ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate gland ■ glaucoma ■ a breathing problem such as emphysema, asthma, or chronic bronchitis

Ask a doctor or pharmacist before use if you are ■ taking the blood thinning drug warfarin ■ taking any other oral nasal decongestant or stimulant ■ taking any other pain reliever/fever reducer ■ taking sedatives or tranquilizers

When using this product ■ do not use more than directed ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children

Stop use and ask a doctor if ■ you get nervous, dizzy, or sleepless ■ pain or nasal congestion gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ redness or swelling is present ■ new symptoms occur

If pregnant or breast-feeding, ask a health professional before use. A Poison Control Center right away. Prompt medical attention is critical for adults as well as for children, even if you do not notice any signs or symptoms.

Drug Facts (continued)

Warnings

■ temporarily relieves minor aches, pains and headache as well as these symptoms of hay fever or other upper respiratory ailments: ■ nasal congestion ■ runny nose ■ sneezing ■ itching of the nose or throat ■ itchy, watery eyes ■ temporarily relieves minor aches, pains, headache and nasal congestion as well as sinus congestion and pressure, and reduces swelling of nasal passages

Warnings

Liver warning: This product contains acetaminophen. More than 12 tablets in any 24-hour period, which is the maximum daily amount, with other drugs containing acetaminophen or 3 or more alcoholic drinks every day while using this product may cause severe skin reactions.

Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ blisters ■ rash

If a skin reaction occurs, stop use and seek medical help right away.

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Drug Facts (continued)

Drug Facts

Active ingredients (in each tablet)

Acetaminophen, USP 325 mg.....Pain reliever/Fever reducer
 Chlorpheniramine maleate, USP 2 mg.....Antihistamine
 Phenylephrine HCl, USP 5 mg.....Nasal decongestant

Purposes

- temporarily relieves these symptoms associated with a cold, or flu: ■ headache ■ nasal congestion ■ sore throat ■ fever ■ minor aches and pains

Uses

Drug Facts (continued)

PA067933

See new warnings information

Dristan® Cold



Acetaminophen >>> Pain reliever/Fever reducer
Chlorpheniramine maleate >>> Antihistamine
Phenylephrine HCl >>> Nasal decongestant

multi-symptom formula

For relief of Nasal Congestion, Sinus Pressure, Headache, Aches and Pains, Fever, Runny Nose and Sneezing

20 COATED TABLETS

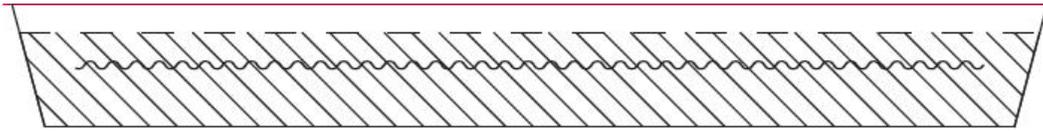
Tablets Individually Blisters Sealed. If seal is broken, Do Not Use.

Distributed by: Pfizer, Madison, NJ 07940 USA
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 For most recent product information, visit www.dristan.com

FPO

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DRISTAN COLD MULTISYMP TOM

acetaminophen, chlorpheniramine maleate, phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0573-1238
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
CHLORPHENIRAMINE MALEATE (UNII: V1Q0O9OJ9Z) (CHLORPHENIRAMINE - UNII:3U6IO1965U)	CHLORPHENIRAMINE MALEATE	2 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CALCIUM STEARATE (UNII: 776XM7047L)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	YELLOW (Upper Yellow Layer) , WHITE (Bottom White Layer)	Score	no score
Shape	ROUND (Round film-coated tablet)	Size	5mm
Flavor		Imprint Code	d
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0573-1238-21	2 in 1 CARTON	09/04/2015	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/05/2005	

Labeler - Wyeth Consumer Healthcare LLC (828831730)

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0573-1238) , LABEL(0573-1238) , MANUFACTURE(0573-1238) , PACK(0573-1238)

Revised: 12/2018

Wyeth Consumer Healthcare LLC